

REMARKS

Office action summary. Claim 10 is rejected for indefiniteness. Claims 1 and 2 are rejected as anticipated by U.S. Patent 6,743,211 (“Prausnitz”). Claims 3-5 and 8-17 are rejected as obvious over Prausnitz.

Applicants greatly appreciate the indication of allowable subject matter in claims 6-7.

The rejections are overcome by the present amendment and otherwise traversed.

Claim amendments. Claim 1 is amended to indicate that the microneedles are comprised of the photoresist. New claims 22-27 are added. Claim 22 is supported, for example, by claim 11 combined with claim 6. Claim 23 is supported by claim 11 combined with originally filed claim 28 of the parent (which was restricted out there). Claims 24 and 25 are supported by originally filed claims 29 and 30 of the parent (also restricted out there). New claim 26 is supported, for example, by the specification as filed, page 11, lines 11-16, and page 32, lines 9-13.

Indefiniteness rejection. Claim 10, which was found indefinite because it lacked antecedent basis, is cancelled.

Anticipation rejections. Newly amended claim 1 recites that the microneedles are comprised of the photoresist, avoiding the purported ambiguity noted by the Examiner whereby the claim “does not positively recite that the photoresist material is in fact the microneedle structure itself.” (Action at 2). At a minimum this limitation overcomes the anticipation rejection, since the fabrication of microneedle arrays comprised of photoresist is not disclosed by Prausnitz.

Obviousness rejections. MPEP § 2142 lists three criteria, all of which must be met in order for there to be a *prima facie* case of obviousness:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Examiner has failed to meet the requirements for a *prima facie* case of obviousness over the Prausnitz reference.

The use of photoresist to make the actual microneedles is nonobvious as shown by the fact that Prausnitz uses photoresist for other purposes but not for actual microneedles. The

inventors recognized that photoresist, which is an unusually malleable and flexible way to make microstructures of different kinds, is suitable for arrays of microneedles. The prior art generally taught the use of silicon, metals, and the like to make microneedle arrays because of the perceived need for stiffness, or if polymeric materials were used one would deposit metals onto them to achieve stiffness, as in Prausnitz. The applicants' use of materials perceived as "softer," such as photoresist, to make microneedles arises from an understanding of the true needs of this mode of drug delivery.

Claim 11 expressly recites that a "patterned photoresist material/substrate" is the master used to make a replica mold – as the claim states, the moldable material is applied onto the "patterned photoresist material/substrate" itself, *not* onto something else derived from that object. While the Examiner has stated generally that claim 11 is obvious, there is no specific discussion in the Action of why the prior art teaches, suggests, or would lead a person of skill in the art to make a master for a replica mold out of photoresist. Again, the prior art tended to view such molds as having to be made of metal or silicon or other stiffer materials which the present inventors found not to be necessary.

In sum, the applicants have made a patentable advance over the prior art which leads to more economical and flexible ways of making microneedle arrays. The obviousness rejection should therefore be withdrawn.

Patentability of new claims. Claim 22 distinguishes over the prior art of record, at a minimum, because it incorporates limitations from claim 6, which the Examiner has kindly indicated comprises patentable subject matter. Claims 23-25 are believed also to be patentable, for example, because the prior art cited by the Examiner does not suggest depositing an electrically conductive substance through a mask onto a microneedle structure as recited in claim 23. Claim 26 is believed also to be patentable because the prior art cited by the Examiner does not discuss detachable microneedles which comprise a different material from their substrate where the material difference between substrate and microneedles facilitates detachment.

Conclusion. If the Examiner has any questions about this response it is respectfully requested that he telephone the undersigned attorney at his direct dial (650) 251-7712.

Respectfully submitted,

By: /Flavio M. Rose/ _____
Flavio M. Rose
Registration No. 40,791
c/o MINTZ LEVIN
1400 Page Mill Road
Palo Alto, California 94304-1124
(650) 251-7700 Telephone
(650) 251-7739 Facsimile
Customer Number 23980

4160610v.1